

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Index No.
05 Cv 00728 (VM)

CAREMARK THERAPEUTIC SERVICES,

ECF CASE

Plaintiff,

PLAINTIFF'S
AFFIDAVIT IN
OPPOSITION

-against-

TOMMY THOMPSON, SECRETARY OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
AND THE CENTERS FOR MEDICARE AND MEDICAID
SERVICES,

Defendants.

STATE OF NEW YORK)
COUNTY OF NEW YORK) SS:

Abraham Wax, being duly sworn, deposes and says that:

1. I am the attorney for the Plaintiff and I am familiar with the facts. I make this affidavit in opposition to the motion made by the defendants to dismiss this action.

2. This is an action by the health care provider, CAREMARK THERAPEUTIC SERVICES, to review decisions made by MEDICARE. All the decisions, made in the process of exhaustion of the administrative remedies, denied payment for treatment of the patient, JANETH ALVARADO, a hemophiliac. All of the treatment was with a blood clotting factor called NOVOSEVEN. The facts in all of the cases were all the same, the only difference were the dates of treatment.

3. The treatment was for a rare form of hemophilia, a deficiency in the patient of BLOOD FACTOR 10. The drug, NOVOSEVEN was approved by the FDA for treating of blood factor 8 and blood factor 9, so the treatment was off-label. Although the FDA approval did not cover treatment for BLOOD FACTOR 10, the FDA does not prohibit off-label treatment. In fact, the FDA permits doctors to prescribe drugs for off-label uses. *Ortho Pharmaceutical Corp. v. Cosprophar, Inc.*, 32 F. 3d 690 (2d Cir 1994).

4. CAREMARK undertook to engage in its administrative remedy when the claim for treatment was denied. In fact there were 4 applications for payment, and 13 unfavorable decisions. If the patient had not been treated with NOVOSEVEN, she would had bled to death. The treatment stopped the bleeding, and she survived. Nevertheless, all 13 unfavorable decisions in effect denied the treatment for "lack of medical necessity". All 13 but one of the decisions were based upon a MEDICARE bulletin dated June 2000, (attached to the brief as EXHIBIT A). This bulletin directed that payment not be made for NOVOSEVEN if it is self-administered - that is, not done under supervision of a doctor or at a hospital. The one decision that does not mention the June 2000 bulletin carries no explanation of the reason for the decision. When CAREMARK sought to discover the reason payment was denied, the MEDICARE carrier had a Lead Medical Review Analyst direct CAREMARK to the bulletin of June 2000.

5. The June 2000 bulletin, the basis of every decision denying payment (except perhaps one of the decisions) was unconstitutional. That bulletin violated

the Social Security statute, 42 U.S.C. §1861 (S)(2)(I) which covers "*blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision . . .*". As we have shown above, the June 2000 states that that blood clotting factor to control bleeding is NOT COVERED, if it is self administered.

That same bulletin of June 2000 also violated 42 CFR § 410.63(b) which covers "*(b) blood clotting factors. Effective July 18, 1984, blood clotting factors to control bleeding for hemophilia patients competent to use these factors without medical or other supervision, and items related to the administration of these factors*".

6. Although MEDICARE did issue another bulletin in December 2001, announcing that that blood clotting factor to control bleeding would be covered (immediately), nobody at the MEDICARE carrier seems to have paid attention to the later bulletin, and, of course, MEDICARE did not see to it that the later bulletin was obeyed, and CAREMARK suffered for it. None of its claims for this patient was paid. (Actually, one set of treatments was paid, but MEDICARE declared an over payment and took the money back). All the denials took place in years 2002 and 2003.

7. Thus, MEDICARE violated the statute and its own regulations by issuing the bulletin of June 2000, a constitutional violation. It also violated the constitution by keeping the bulletin on the books. That bulletin is still on the books for all its 'deciders' to see and use. Although the bulletin of December 2001 is on the books, and although it mentions the June 2000 bulletin, there is nothing in the June

2000 bulletin that refers to the December 2001 bulletin, or that suggests that there is a denial of due process. I would imagine that when MEDICARE sees this set of papers they will take steps to eliminate the June 2000 bulletin from the record.

8. It is true that there has not been an adjudication that the June 2000 bulletin represents a constitutional violation. However, this action will seek to declare that enacting the bulletin, and keeping it on the books to date, is a violation of the constitution and due process, and we intend to pursue this.

9. There are other due process violations set forth in our brief, such as failure to give credence to the treating physician, using the wrong law, and having the Lead Medical Analyst mislead CAREMARK by citing the wrong law.

10. While it is true that with respect to two of the claims CAREMARK failed to exhaust its administrative remedies, it certainly would have been futile to do so given that there are serious constitutional issues. Pursuing administrative remedies is certainly futile when there have been such constitutional issues - the administrative agencies are not the proper entities to resolve constitutional issues. They are the ones, in this case, who have violated the constitution. Under such circumstances, it would be futile to exhaust the administrative remedies - the Courts are the proper entities to examine constitutional issues.

11. This action was brought in New York. The statute, U.S.C. 42 § 405 (g) is the venue statute. That statute allows the action to be brought where the plaintiff resides. Plaintiff resides in all 50 states. The real party in interest is CAREMARK RX, Inc., the parent corporation. CAREMARK RX, Inc., is registered to

do business in New York, and has an additional presence through about 7 subsidiary corporations. Although the Court may remove the case to a more convenient forum, the defendants have failed to show that there is any more convenient forum. This Court should not remove the case from a forum chosen by the plaintiff.

WHEREFORE, PLAINTIFF requests that this Court deny defendant's motion to dismiss.

/S/

Abraham Wax
Attorney for Plaintiff

Sworn to before me this
15 day of June, 2005.

/S/

Notary Public